



Reprinted
January 29, 2016

SENATE BILL No. 41

DIGEST OF SB 41 (Updated January 28, 2016 2:08 pm - DI 97)

Citations Affected: IC 5-10; IC 27-8; IC 27-13.

Synopsis: Pharmacy benefits. Requires a state employee health plan, an accident and sickness insurer, and a health maintenance organization to make available a procedure for a covered individual's use in requesting an exception to a step therapy protocol used by the state employee health plan, accident and sickness insurer, or health maintenance organization with respect to coverage for certain prescription drugs, including time frames for a determination concerning an exception and reasons for granting an exception.

Effective: July 1, 2016.

**Crider, Brown L, Stoops,
Randolph Lonnie M**

January 5, 2016, read first time and referred to Committee on Rules & Legislative Procedure.
January 11, 2016, amended; reassigned to Committee on Health & Provider Services.
January 21, 2016, amended, reported favorably — Do Pass.
January 28, 2016, read second time, amended, ordered engrossed.

SB 41—LS 6169/DI 13



Reprinted
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Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

SENATE BILL No. 41

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

- 1 SECTION 1. IC 5-10-8-17 IS ADDED TO THE INDIANA CODE
2 AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
3 1, 2016]: **Sec. 17. (a) As used in this section, "covered individual"**
4 **means an individual entitled to coverage under a state employee**
5 **health plan.**
6 **(b) As used in this section, "medical necessity" or "medically**
7 **necessary" means appropriateness, or appropriate, under the**
8 **standard of care that applies to a covered individual's condition:**
9 **(1) to improve, preserve, or slow the deterioration of the**
10 **covered individual's health, life, or function; or**
11 **(2) for the early screening, prevention, evaluation, diagnosis,**
12 **or treatment of the covered individual's condition or injury.**
13 **(c) As used in this section, "preceding prescription drug" means**
14 **a prescription drug that, according to a step therapy protocol,**
15 **must be:**
16 **(1) first used to treat a covered individual's condition; and**
17 **(2) as a result of the treatment under subdivision (1),**

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determined to be inappropriate to treat the covered individual's condition; as a condition of coverage under a state employee health plan for succeeding treatment with another prescription drug.

(d) As used in this section, "protocol exception" means a determination by a state employee health plan that, based on a review of a request for the determination and any supporting documentation:

- (1) a step therapy protocol is not medically appropriate for treatment of a particular covered individual's condition; and
- (2) the state employee health plan will:
 - (A) not require the covered individual's use of a preceding prescription drug under the step therapy protocol; and
 - (B) provide immediate coverage for another prescription drug that is prescribed for the covered individual.

(e) As used in this section, "state employee health plan" refers to the following that provide coverage for prescription drugs:

- (1) A self-insurance program established under section 7(b) of this chapter.
- (2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

The term includes a person that administers prescription drug benefits on behalf of a state employee health plan.

(f) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a state employee health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition.

(g) A state employee health plan shall publish on the state employee health plan's Internet web site, and provide to a covered individual in writing, a procedure for the covered individual's use in requesting a protocol exception. The procedure must include the following provisions:

- (1) A description of the manner in which a covered individual may request a protocol exception.
- (2) That the state employee health plan shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:
 - (A) in the case of an emergency, twenty-four (24) hours after receiving the request or appeal; or
 - (B) in the case of a nonemergency, seventy-two (72) hours after receiving the request or appeal.



(3) That a protocol exception will be granted if any of the following apply, as determined by the covered individual's treating health care provider:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the covered individual.

(B) A preceding prescription drug is expected to be ineffective based on the known clinical characteristics of the covered individual and the known characteristics of the prescription drug regimen.

(C) The covered individual has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on medical necessity, a preceding prescription drug is not in the best interest of the covered individual.

(E) The covered individual's condition is currently stable on a prescription drug prescribed by the covered individual's health care provider before implementation or applicability of the step therapy protocol.

(4) That when a protocol exception is granted, the state employee health plan shall notify the covered individual and the covered individual's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(h) This section does not do the following:

(1) Prevent a state employee health plan from requiring a covered individual to use a generic prescription drug that has been classified by the federal Food and Drug Administration and published in its Approved Drug Products with Therapeutic Equivalence Evaluations list as having a therapeutic equivalence evaluation of "AB" with the prescribed brand name prescription drug before providing coverage for the prescribed brand name prescription drug.

(2) Prevent a health care provider from prescribing a prescription drug that is determined to be medically necessary.

SECTION 2. IC 27-8-5-30 IS ADDED TO THE INDIANA CODE



1 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
2 1, 2016]: Sec. 30. (a) As used in this section, "insured" means an
3 individual who is entitled to coverage under a policy of accident
4 and sickness insurance.

5 (b) As used in this section, "insurer" refers to an insurer that
6 issues a policy of accident and sickness insurance. The term
7 includes a person that administers prescription drug benefits on
8 behalf of an insurer.

9 (c) As used in this section, "medical necessity" or "medically
10 necessary" means appropriateness, or appropriate, under the
11 standard of care that applies to an insured's condition:

12 (1) to improve, preserve, or slow the deterioration of the
13 insured's health, life, or function; or

14 (2) for the early screening, prevention, evaluation, diagnosis,
15 or treatment of the insured's condition or injury.

16 (d) As used in this section, "policy of accident and sickness
17 insurance" means a policy of accident and sickness insurance that
18 provides coverage for prescription drugs.

19 (e) As used in this section, "preceding prescription drug" means
20 a prescription drug that, according to a step therapy protocol,
21 must be:

22 (1) first used to treat an insured's condition; and

23 (2) as a result of the treatment under subdivision (1),
24 determined to be inappropriate to treat the insured's
25 condition;

26 as a condition of coverage under a policy of accident and sickness
27 insurance for succeeding treatment with another prescription
28 drug.

29 (f) As used in this section, "protocol exception" means a
30 determination by an insurer that, based on a review of a request
31 for the determination and any supporting documentation:

32 (1) a step therapy protocol is not medically appropriate for
33 treatment of a particular insured's condition; and

34 (2) the insurer will:

35 (A) not require the insured's use of a preceding
36 prescription drug under the step therapy protocol; and

37 (B) provide immediate coverage for another prescription
38 drug that is prescribed for the insured.

39 (g) As used in this section, "step therapy protocol" means a
40 protocol that specifies, as a condition of coverage under a policy of
41 accident and sickness insurance, the order in which certain
42 prescription drugs must be used to treat an insured's condition.



(h) An insurer shall publish on the insurer's Internet web site, and provide to an insured in writing, a procedure for the insured's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an insured may request a protocol exception.

(2) That the insurer shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in the case of an emergency, twenty-four (24) hours after receiving the request or appeal; or

(B) in the case of a nonemergency, seventy-two (72) hours after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply, as determined by the insured's treating health care provider:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.

(B) A preceding prescription drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics of the prescription drug regimen.

(C) The insured has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on medical necessity, a preceding prescription drug is not in the best interest of the insured.

(E) The insured's condition is currently stable on a prescription drug prescribed by the insured's health care provider before implementation or applicability of the step therapy protocol.

(4) That when a protocol exception is granted, the insurer shall notify the insured and the insured's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(i) This section does not do the following:



(1) Prevent an insurer from requiring an insured to use a generic prescription drug that has been classified by the federal Food and Drug Administration and published in its Approved Drug Products with Therapeutic Equivalence Evaluations list as having a therapeutic equivalence evaluation of "AB" with the prescribed brand name prescription drug before providing coverage for the prescribed brand name prescription drug.

(2) Prevent a health care provider from prescribing a prescription drug that is determined to be medically necessary.

SECTION 3. IC 27-13-7-23 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 23. (a) As used in this section, "group contract" refers to a group contract that provides coverage for prescription drugs.

(b) As used in this section, "health maintenance organization" refers to a health maintenance organization that provides coverage for prescription drugs. The term includes the following:

(1) A limited service health maintenance organization.

(2) A person that administers prescription drug benefits on behalf of a health maintenance organization or a limited service health maintenance organization.

(c) As used in this section, "individual contract" refers to an individual contract that provides coverage for prescription drugs.

(d) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to an enrollee's condition:

(1) to improve, preserve, or slow the deterioration of the enrollee's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the enrollee's condition or injury.

(e) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an enrollee's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the enrollee's condition;

as a condition of coverage under an individual contract or a group contract for succeeding treatment with another prescription drug.

(f) As used in this section, "protocol exception" means a



determination by a health maintenance organization that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular enrollee's condition; and

(2) the health maintenance organization will:

(A) not require the enrollee's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the enrollee.

(g) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under an individual contract or a group contract, the order in which certain prescription drugs must be used to treat an enrollee's condition.

(h) A health maintenance organization shall publish on the health maintenance organization's Internet web site, and provide to an enrollee in writing, a procedure for the enrollee's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an enrollee may request a protocol exception.

(2) That the health maintenance organization shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in the case of an emergency, twenty-four (24) hours after receiving the request or appeal; or

(B) in the case of a nonemergency, seventy-two (72) hours after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply, as determined by the enrollee's treating health care provider:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the enrollee.

(B) A preceding prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen.

(C) The enrollee has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same



1 pharmacologic class or has the same mechanism of
2 action as a preceding prescription drug;
3 and the prescription drug was discontinued due to lack of
4 efficacy or effectiveness, diminished effect, or an adverse
5 event.

6 (D) Based on medical necessity, a preceding prescription
7 drug is not in the best interest of the enrollee.

8 (E) The enrollee's condition is currently stable on a
9 prescription drug prescribed by the enrollee's health care
10 provider before implementation or applicability of the step
11 therapy protocol.

12 (4) That when a protocol exception is granted, the health
13 maintenance organization shall notify the enrollee and the
14 enrollee's health care provider of the authorization for
15 coverage of the prescription drug that is the subject of the
16 protocol exception.

17 (i) This section does not do the following:

18 (1) Prevent a health maintenance organization from requiring
19 an enrollee to use a generic prescription drug that has been
20 classified by the federal Food and Drug Administration and
21 published in its Approved Drug Products with Therapeutic
22 Equivalence Evaluations list as having a therapeutic
23 equivalence evaluation of "AB" with the prescribed brand
24 name prescription drug before providing coverage for the
25 prescribed brand name prescription drug.

26 (2) Prevent a health care provider from prescribing a
27 prescription drug that is determined to be medically
28 necessary.



COMMITTEE REPORT

Madam President: The Senate Committee on Rules and Legislative Procedure, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Delete everything after the enacting clause and insert the following:

(SEE TEXT OF BILL)

and when so amended that said bill be reassigned to the Senate Committee on Health & Provider Services.

(Reference is to SB 41 as introduced.)

LONG, Chairperson

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 4, line 19, delete ":" and insert "**, as determined by the covered individual's treating health care provider:**".

Page 8, line 6, delete ":" and insert "**, as determined by the insured's treating health care provider:**".

Page 11, line 38, delete ":" and insert "**, as determined by the enrollee's treating health care provider:**".

and when so amended that said bill do pass.

(Reference is to SB 41 as printed January 12, 2016.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 10, Nays 1.

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SENATE MOTION

Madam President: I move that Senate Bill 41 be amended to read as follows:

- Page 1, line 3, delete "(a) As used in this section, "clinical practice".
- Page 1, delete lines 4 through 6.
- Page 1, line 7, delete "(b)" and insert "**(a)**".
- Page 1, delete lines 9 through 10.
- Page 1, line 11, delete "(d)" and insert "**(b)**".
- Page 2, line 1, delete "(e)" and insert "**(c)**".
- Page 2, line 10, delete "(f)" and insert "**(d)**".
- Page 2, line 21, delete "(g)" and insert "**(e)**".
- Page 2, line 29, delete "(h)" and insert "**(f)**".
- Page 2, delete lines 33 through 42.
- Page 3, delete lines 1 through 39.
- Page 3, line 40, delete "(k)" and insert "**(g)**".
- Page 4, delete lines 13 through 17.
- Page 4, line 18, delete "(4)" and insert "**(3)**".
- Page 4, line 21, delete "Following the step therapy protocol" and insert "**A preceding prescription drug**".
- Page 4, line 42, delete "(5)" and insert "**(4)**".
- Page 5, line 5, delete "(l)" and insert "**(h)**".
- Page 5, delete lines 17 through 18.
- Page 5, line 21, delete "(a) As used in this section, "clinical practice".
- Page 5, delete lines 22 through 26.
- Page 5, line 27, delete "(c)" and insert "**(a)**".
- Page 5, line 30, delete "(d)" and insert "**(b)**".
- Page 5, line 34, delete "(e)" and insert "**(c)**".
- Page 5, line 41, delete "(f)" and insert "**(d)**".
- Page 6, line 2, delete "(g)" and insert "**(e)**".
- Page 6, line 12, delete "(h)" and insert "**(f)**".
- Page 6, line 22, delete "(i)" and insert "**(g)**".
- Page 6, delete lines 26 through 42.
- Page 7, delete lines 1 through 30.
- Page 7, line 31, delete "(l)" and insert "**(h)**".
- Page 8, delete lines 2 through 5.
- Page 8, line 6, delete "(4)" and insert "**(3)**".
- Page 8, line 9, delete "Following the step therapy protocol" and insert "**A preceding prescription drug**".
- Page 8, line 30, delete "(5)" and insert "**(4)**".
- Page 8, line 34, delete "(m)" and insert "**(i)**".



Page 9, delete lines 4 through 5.
 Page 9, line 8, delete "(a) As used in this section, "clinical practice".
 Page 9, delete lines 9 through 11.
 Page 9, line 12, delete "(b)" and insert "**(a)**".
 Page 9, line 14, delete "(c)" and insert "**(b)**".
 Page 9, line 21, delete "(d)" and insert "**(c)**".
 Page 9, line 23, delete "(e)" and insert "**(d)**".
 Page 9, line 30, delete "(f)" and insert "**(e)**".
 Page 9, line 39, delete "(g)" and insert "**(f)**".
 Page 10, line 8, delete "(h)" and insert "**(g)**".
 Page 10, delete lines 12 through 42.
 Page 11, delete lines 1 through 18.
 Page 11, line 19, delete "(k)" and insert "**(h)**".
 Page 11, delete lines 34 through 38.
 Page 11, line 39, delete "(4)" and insert "**(3)**".
 Page 11, line 42, delete "Following the step therapy protocol" and
 insert "**A preceding prescription drug**".
 Page 12, line 21, delete "(5)" and insert "**(4)**".
 Page 12, line 26, delete "(m)" and insert "**(i)**".
 Page 12, delete lines 38 through 39.

(Reference is to SB 41 as printed January 22, 2016.)

CRIDER

